

EPA NEW ENGLAND
QUALITY ASSURANCE
PROJECT PLAN PROGRAM GUIDANCE



U.S. EPA NEW ENGLAND
Quality Assurance Unit
Office of Environmental Measurement and Evaluation

April 2005

Preface

The EPA New England Quality Assurance Unit implements a Quality Assurance Project Plan (QAPP) Program in accordance with EPA Order 5360.1 A2, May 2000. Among other requirements, the “QA Order” requires the development, review and approval of QAPPs for all environmental data operations performed by or for EPA. The term “environmental data operations” refers to activities involving the collection, generation, compilation, analysis, evaluation and use of environmental data. The *EPA New England Quality Assurance Project Plan Program Guidance* document implements national QAPP requirements specified in *EPA Requirements for Quality Assurance Project Plans* (EPA QA/R-5), and the *EPA Quality Manual for Environmental Programs*, 5360 A1.

As a regional implementation document, the *EPA New England Quality Assurance Project Plan Program Guidance*

- Outlines a regional planning process to ensure project quality objectives are systematically identified
- Defines a minimum set of project QA/QC activities that must be described in a QAPP to ensure that data collected by or for EPA New England are of known and documented quality and can be used in environmental decision making
- Describes the roles and responsibilities of project management and personnel

| Program | Guidance |
|--|---|
| General | <i>EPA Guidance for Quality Assurance Project Plans</i> (EPA QA/G-5), December 2002, EPA/240/R-02/009, http://www.epa.gov/quality/qa_docs.html |
| Water Quality Monitoring | <i>The Volunteer Monitor's Guide to Quality Assurance Project Plans</i> , September 1996, EPA/841/B-96/003, http://epa.gov/owow/monitoring/volunteer/qapp/vol_qapp.pdf |
| Wadeable Streams and Rivers | <i>Generic Quality Assurance Project Plan Guidance for Programs Using Community Level Biological Assessments in Wadeable Streams and Rivers</i> , http://www.epa.gov/bioindicators/html/qapp.html |
| Brownfields | <i>Quality Assurance Guidance for Conducting Brownfields Site Assessments</i> , September 1998, EPA 540-R-98-038, http://www.epa.gov/swerosps/bf/pdf/bfqag4.pdf |
| Hazardous Waste (Federal Facilities, Superfund, and RCRA) | <i>Uniform Federal Policy for Quality Assurance Project Plans</i> , July 2004, OSWER Directive 9272.0-17 http://www.epa.gov/fedfac/pdf/ufp_manualv1_july04.pdf |
| Air | Ambient Monitoring Technology Information Center http://www.epa.gov/ttn/amtic/ |
| Pesticides | <i>Guidance for Quality Assurance Project Plans-Development for EPA Funded Cooperative Agreements with State and Tribal Agencies for the Conduct of FIFRA Pesticide Programs</i> , December 15, 2000 http://www.epa.gov/region9/qa/pdfs/finalqaappver9.pdf |

Table of Contents

| | | |
|------------|---|----------|
| 1.0 | INTRODUCTION | 2 |
| 2.0 | SCOPE | 3 |
| 3.0 | REQUIRED QAPP ELEMENTS | 3 |
| 4.0 | ROLES AND RESPONSIBILITIES | 5 |
| 5.0 | QAPP REVIEW AND APPROVAL..... | 6 |
| 6.0 | IMPLEMENTATION OF APPROVED QAPP | 7 |
| 7.0 | REVISION AND MODIFICATION OF APPROVED QAPP | 7 |
| 8.0 | QAPP ARCHIVAL | 8 |
| 9.0 | REFERENCES | 9 |

EPA NEW ENGLAND QUALITY ASSURANCE PROJECT PLAN PROGRAM GUIDANCE

1.0 INTRODUCTION

A quality assurance project plan (QAPP) is a required planning document that provides a “blueprint” for obtaining the type, quantity and quality of data needed to support environmental decision making. The QAPP documents all quality assurance (QA), quality control (QC) and technical activities and procedures associated with planning, implementing and assessing environmental data operations, Figure 1.

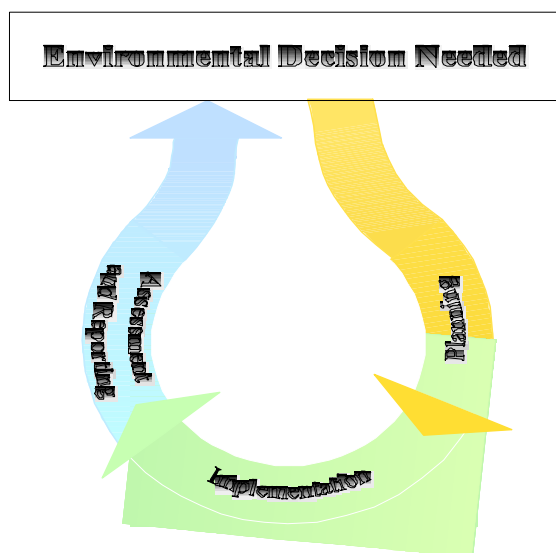


Figure 1. Life Cycle of an Environmental Data Operation

EPA New England (EPA NE) recognizes the following two types of QAPPs:

1. “Project-specific QAPPs” provide a QA blueprint specific to one project or task. Project-specific QAPPs are used when projects are limited in scope and time and, in general, can be considered the sampling and analysis plan/workplan for the project.
2. “Generic program QAPPs” provide an overarching plan that describes a program's quality objectives and document the comprehensive set of sampling, analysis, QA/QC, data review, and assessment procedures specific to one program or group. In contrast to the project-specific QAPP, the generic program QAPP serves as an umbrella under which multiple project-specific tasks may be conducted over an extended period of time. Project or task-specific information, not covered by the umbrella, is documented in detailed sampling and analysis plans/workplans, which use the generic program QAPP as an informational reference.

EPA Order 5360.1 A2 requires that a QAPP be prepared and approved for all environmental data operations performed by or for EPA prior to the initiation of those data operations. In addition to the QAPP requirement, this Order mandates that quality systems be in place to support the development, review, approval, implementation and assessment of data operations and to ensure that environmental technologies are designed, constructed, and operated according to defined expectations. EPA NE designates those organizations performing work for or on behalf of EPA as “Lead Organizations.” Lead Organizations include organizations performing work under financial assistance agreements and in response to voluntary, consensual or unilateral enforcement agreements, decrees and orders. Lead Organizations are required to develop, operate and document their quality system in quality management plans (QMPs) to ensure that environmental data collected and used by the Agency are of known and documented quality and are suitable for their intended use.

Guidance for developing quality systems is provided in *Quality Systems for Environmental Data and Technology Programs - Requirements with Guidance for Use*, American National Standard, (ANSI/ASQ E4 - 2004) February 2004; *EPA Requirements for Quality Management Plans*, EPA QA/R-2, March 2001; and *EPA Quality Manual for Environmental Programs*, 5360 A1, May 5, 2000.

2.0 SCOPE

The *EPA New England Quality Assurance Project Plan Program Guidance* (hereafter referred to as the *EPA NE QAPP Program*) is based on Agency requirements as outlined in *EPA Requirements for Quality Assurance Project Plans*, EPA QA/R-5, March, 2001. The *EPA NE QAPP Program* provides the framework for all project-specific and generic program QAPPs. It is a companion guidance to other documents written by the EPA NE Quality Assurance Unit which are available at <http://epa.gov/ne/lab/qa/qualsys.html>. These documents form the basis of the EPA NE quality system that supports the generation, collection and use of scientifically defensible data. Program-specific QAPP guidance documents, listed on page ii, should be used when so directed by the environmental program office. General QAPP guidance is provided in *EPA Guidance for Quality Assurance Project Plans*, EPA QA/G-5.

Since the content and level of detail in individual QAPPs will vary according to the work being performed and the intended use of the data, EPA NE supports a “graded approach” when preparing QAPPs. In other words, the amount of documentation and level of detail will vary based upon the complexity and cost of the project. Appropriate consideration should be given to the significance of the environmental problem to be investigated, the environmental decision to be made, and the impact on human health and the environment.

3.0 REQUIRED QAPP ELEMENTS

In accordance with EPA QA/R-5, there are four basic element groups that must be addressed in a QAPP, as depicted in Figure 2. In order to piece these interrelated element groups together to meet project objectives, a systematic planning process, similar to the one outlined in Figure 3, should be used to determine project tasks and to select technical and QA/QC activities.

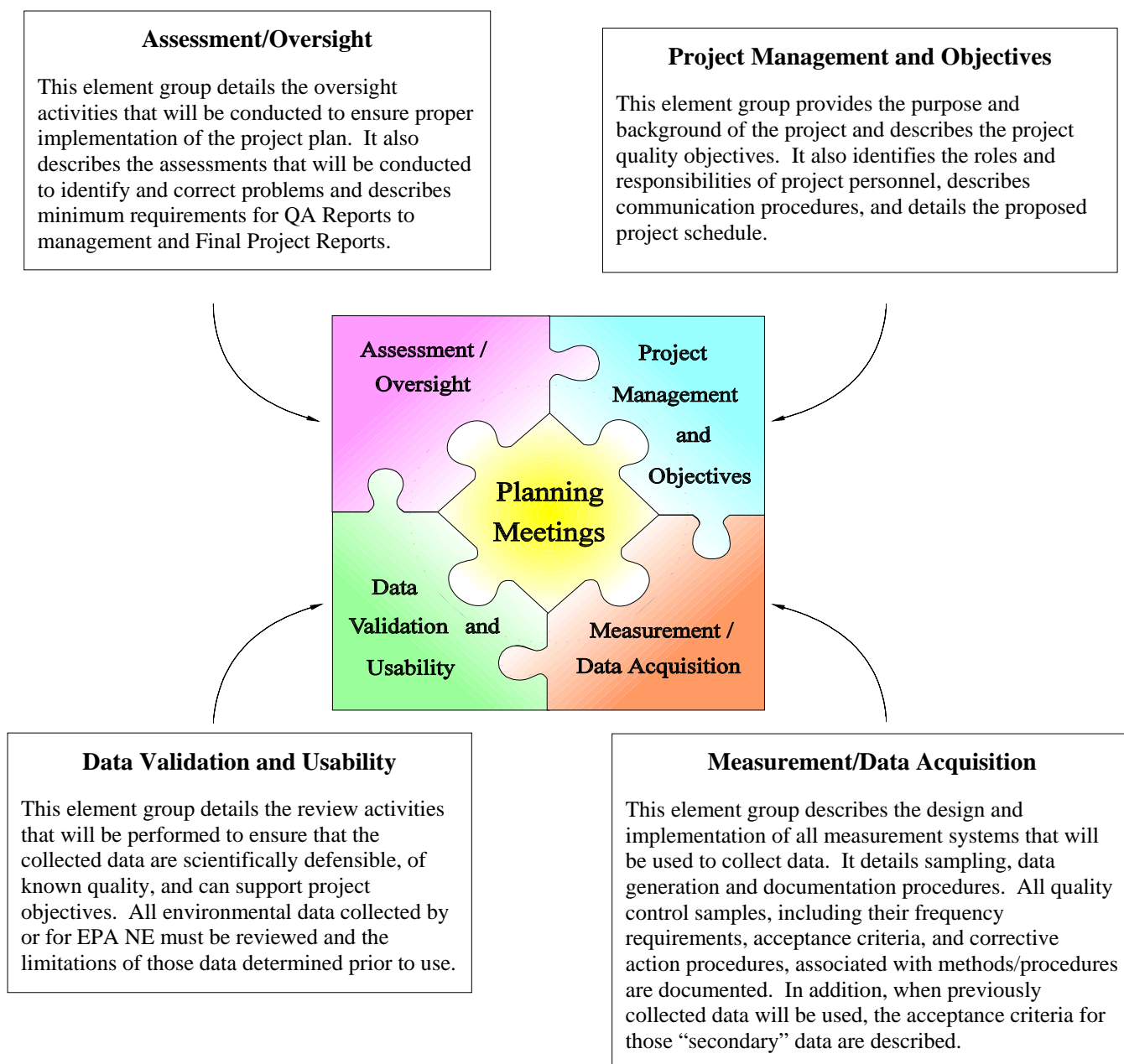


Figure 2. Required QAPP Element Groups

Specific requirements for each element group are detailed in program-specific QAPP guidance documents listed on page ii. If some or all of the required QAPP elements are incorporated into other planning documents (i.e., Sampling and Analysis Plans [SAPs], Field Sampling Plans [FSPs], Field Operations Plans [FOPs], Project Operations Plans [POPs] or general Project Workplans [WPs]), then a cross-reference table should be provided to identify where the required QAPP elements are located. The referenced SAP, FSP, etc., should be identified with the document title, date, section number, and page numbers.

4.0 ROLES AND RESPONSIBILITIES

Lead Organization

The Lead Organization is responsible and accountable for all phases of the project. The Lead Organization may perform the project work directly or contract for field sampling, analytical, data validation, data usability assessment, and oversight assessment services.

The Lead Organization is responsible for ensuring that there is an approved QAPP in place prior to beginning any environmental data operation. Also, the Lead Organization is responsible for ensuring that organization personnel, contractors and/or subcontractors perform project work as prescribed in the approved QAPP. To that end, Lead Organizations should plan and conduct oversight assessments, such as technical system audits (TSAs), of project activities.

Lead Organizations may include the following:

- EPA NE
- Other Federal agencies under interagency agreements, Federal facility agreements, and memoranda of understanding (MOUs) with EPA NE
- States, tribes and local governments under financial assistance agreements with EPA, including grants and cooperative agreements
- Non-profit organizations under financial assistance agreements with EPA NE, including institutions of higher education, hospitals, volunteer organizations, and interstate associations
- Regulated facilities (e.g., potentially responsible parties) under voluntary or enforcement consent decrees, agreements and orders with EPA NE

Project Manager

The project manager is responsible for directing, coordinating, and overseeing all project activities for the Lead Organization. He/she is responsible for submitting the QAPP, QAPP amendments, revisions and annual review letters to appropriate personnel, with sufficient lead time, for review and approval. QAPPs should be submitted to EPA NE for review and approval no less than 30 days in advance of the scheduled environmental data operation. The project manager ensures that all technical issues identified during QA review are satisfactorily addressed and documented prior to beginning of field work. Refer to Figure 4 for an outline of the QAPP development process.

Project Team

The project manager assembles a project team consisting of technical personnel including data generators, QA scientists, and data users to plan the project. The size of the project team should reflect the complexity of the project. For example, small volunteer monitoring projects may have project teams comprised of only two or three people.

Planning (scoping) meetings are convened to identify the project objectives; environmental decisions that will be made with the collected data; project action limits; type and quantity of data;

and how "good" the data must be (the data quality) to support the decisions that will be made. The project team defines the quality of the data by setting acceptability limits for the project, otherwise known as measurement performance criteria. Once the measurement performance criteria have been decided upon, the project team can select sampling and analytical methods that have appropriate quantitation limits and quality control limits to achieve project objectives.

The project team is responsible for compiling project information as defined in the program-specific QAPP guidance (page ii) and for resolving all technical issues prior to the preparation of the QAPP document. **Ultimately, it is the responsibility of the project team, and not the QAPP preparer alone, to design a QA "blueprint" that meets project objectives.**

The QAPP should be written by members of the project team experienced in many aspects of environmental science including chemistry, engineering, hydrogeology and risk assessment. In addition, they should be familiar with the sample collection procedures, analytical methods and data review and assessment procedures that will be used for the project.

Project Personnel

An organizational chart, or detailed discussion, should clearly indicate the reporting relationships between EPA NE and project personnel, including contractors and subcontractors. All project personnel are responsible for reading and understanding the QAPP before beginning field work, and for implementing the QAPP as prescribed.

EPA NE QA Unit

The EPA NE QA Unit is responsible for reviewing and approving all intramural and extramural QAPPs, except in the case where the review and approval authority has been delegated by the EPA NE regional quality assurance manager (RQAM) in accordance with Section 5.2.

Members of the QA Unit are available to provide assistance and QA/QC guidance during the planning and implementation of environmental projects. In addition, they perform technical system audits and data review activities.

The QA Unit is also responsible for identifying the QA/QC training needs for the region, including project planning and QAPP training, and for conducting assessments of environmental programs.

5.0 QAPP REVIEW AND APPROVAL

5.1 Internal Review and Approval

The Lead Organization is responsible for ensuring that the QAPP includes all required QAPP elements and information and that project quality objectives (PQOs), technical activities and supporting QA/QC will result in data of known and documented quality that can be used in environmental decision making. To that end, the Lead Organization should review the QAPP and require that all project personnel, contractors, and subcontractors review applicable sections of the QAPP to ensure technical accuracy prior to submitting the QAPP to EPA NE for approval.

5.2 EPA NE Review and Approval

As specified in EPA Order 5360.1 A2, EPA NE must review and approve all intramural and extramural QAPPs before environmental data operations can begin. To that end, a technical review is performed by the QA Unit and the project officer/project manager to ensure that project quality objectives, technical tasks, and supporting QA/QC activities will result in data of known and documented quality that can be used in making environmental decisions. All comments provided by EPA NE must be acceptably addressed in writing before environmental data operations can begin. The response document (either a revised QAPP or letter responding to specific deficiencies) should provide identifying information, as it is presented on the “title and approval page” of the original QAPP.

In accordance with the QA Order, the RQAM has delegated QAPP approval authority to the Superfund and RCRA Corrective Action Programs within EPA NE, as described in Appendix 12 of the EPA NE QMP. As a condition of this delegated authority, the program is required to provide to the QA Unit a copy of the “title and approval page” for each approved QAPP.

The RQAM may also delegate QAPP approval authority to non-EPA organizations in conjunction with the EPA NE environmental program(s). Delegation of this approval authority is contingent upon having an EPA-approved QMP and an effectively implemented quality system.

6.0 IMPLEMENTATION OF APPROVED QAPP

The approved QAPP must be implemented as prescribed; however, the QAPP may be modified at any time after undergoing the proper approval process, to ensure project objectives are met.

7.0 REVISION AND MODIFICATION OF APPROVED QAPP

QAPPs are approved for a fixed period of time specific to the environmental data operation. They must be kept current and revised whenever necessary and when so directed by EPA NE or national program office.

7.1 Modification of Approved QAPP

When procedures or project activities need to be modified to achieve project quality objectives, the QAPP must be amended (e.g., change of sampling locations, methods, matrices, QC samples). This amendment must be reviewed and approved in the same manner as the original QAPP. The amendment should contain complete identifying information, as presented on the original QAPP title and approval page, with updated signatures and dates. Amendments should be approved before changes are implemented.

Verbal approval of modifications may be obtained to expedite project work. Descriptions of modifications and verbal approvals must be documented in telephone logs or emails which are retained in the project file. Subsequently, this verbally approved modification must be documented in an amendment to the QAPP and submitted to EPA NE within seven working days, or on a mutually agreed upon date, for formal signature approval.

Note that when “minor” changes are made to a QAPP (e.g., extending the monitoring period, adding a sampling station), approved amendments are not required. Instead, EPA should be notified by email of all changes and a letter documenting the changes or revised QAPP pages should be sent as a follow up.

7.2 Annual Review of Approved QAPP

Approved QAPPs must be reviewed annually by the Lead Organization, and this annual review should be documented in a letter to the EPA NE RQAM. The annual review letter should describe all changes to the QAPP and/or include revised QAPP pages. If extensive revisions are necessary, greater than ten pages, then a revised QAPP document should be submitted.

8.0 QAPP ARCHIVAL

All QAPPs, reviewers' comments, and responses to reviewers' comments (revised QAPPs, QAPP amendments, and response letters addressing specific issues) must be archived in the appropriate project/program file according to the procedures specified by the Lead Organization in the QAPP and/or their QMP.

Project files must be retained for the period of time specified in the interagency agreement, MOU, cooperative agreement, financial assistance agreement, contract, or voluntary or enforcement consent decree, agreement or order.

EPA NE retains the authority to request project/program files for any extramural project/program during the period of performance of the extramural agreement.

9.0 REFERENCES

1. *Quality Systems for Environmental Data and Technology Programs - Requirements with Guidance for Use*, American National Standard, (ANSI/ASQ E4 -2004), February 2004
2. *EPA Requirements for Quality Management Plans*, March 2001, (EPA QA/R-2) EPA/240/B-01/002, <http://www.epa.gov/quality/qs-docs/r2-final.pdf>
3. *Overview of the EPA Quality System for Environmental Data and Technology*, November 2002, EPA/240/R-02/003, <http://www.epa.gov/quality/qs-docs/overview-final.pdf>
4. March 2, 1999 Memorandum From Norine E. Noonan (AA) to Assistant Administrators and Regional Administrators Re: Clarification of Terminology for the EPA Quality System with attachments
5. *EPA Requirements for Quality Assurance Project Plans*, March 2001, (EPA QA/R-5), EPA/240/B-01/003, <http://www.epa.gov/quality/qs-docs/r5-final.pdf>
6. *EPA Guidance for Quality Assurance Project Plans*, December 2002, (EPA QA/G-5), EPA/240/R-02/009, <http://www.epa.gov/quality/qs-docs/g5-final.pdf>
7. *Guidance for the Data Quality Objective Process*, EPA/600/R-98/018, February 1998, (EPA QA/G-4), EPA/600/R-96/055, <http://www.epa.gov/quality/qs-docs/g4-final.pdf>
8. *EPA New England Quality Management Plan*, May 5, 2005 <http://epa.gov/ne/lab/qa/qualsys.html>
9. *Region 1, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses*, December 1996, <http://epa.gov/ne/lab/qa/qualsys.html>
10. *Region 1, EPA NE Assessment Program*, February 2002.
11. *Guidance for the Preparation of Standard Operating Procedures for Quality-Related Operations*, November 1995, (EPA QA/G-6), EPA/600/R-96/027, <http://www.epa.gov/quality/qs-docs/g6-final.pdf>
12. *Guidance for Data Quality Assessment: Practical Methods for Data Analysis*, July 2000 (EPA QA/G-9), EPA/600/R-96/084, <http://www.epa.gov/quality/qs-docs/g9-final.pdf>
13. *National Enforcement Investigations Center (NEIC) Policies and Procedures*, EPA-330/9-78-001-R, May 1978, Rev. December 1981 NTIS: 1-800-553-6847
14. *Implementation of Quality Assurance Requirements for Organizations Receiving EPA Financial Assistance* <http://www.epa.gov/ogd/qa.htm>

Figure 3. EPA NE Systematic Planning Process

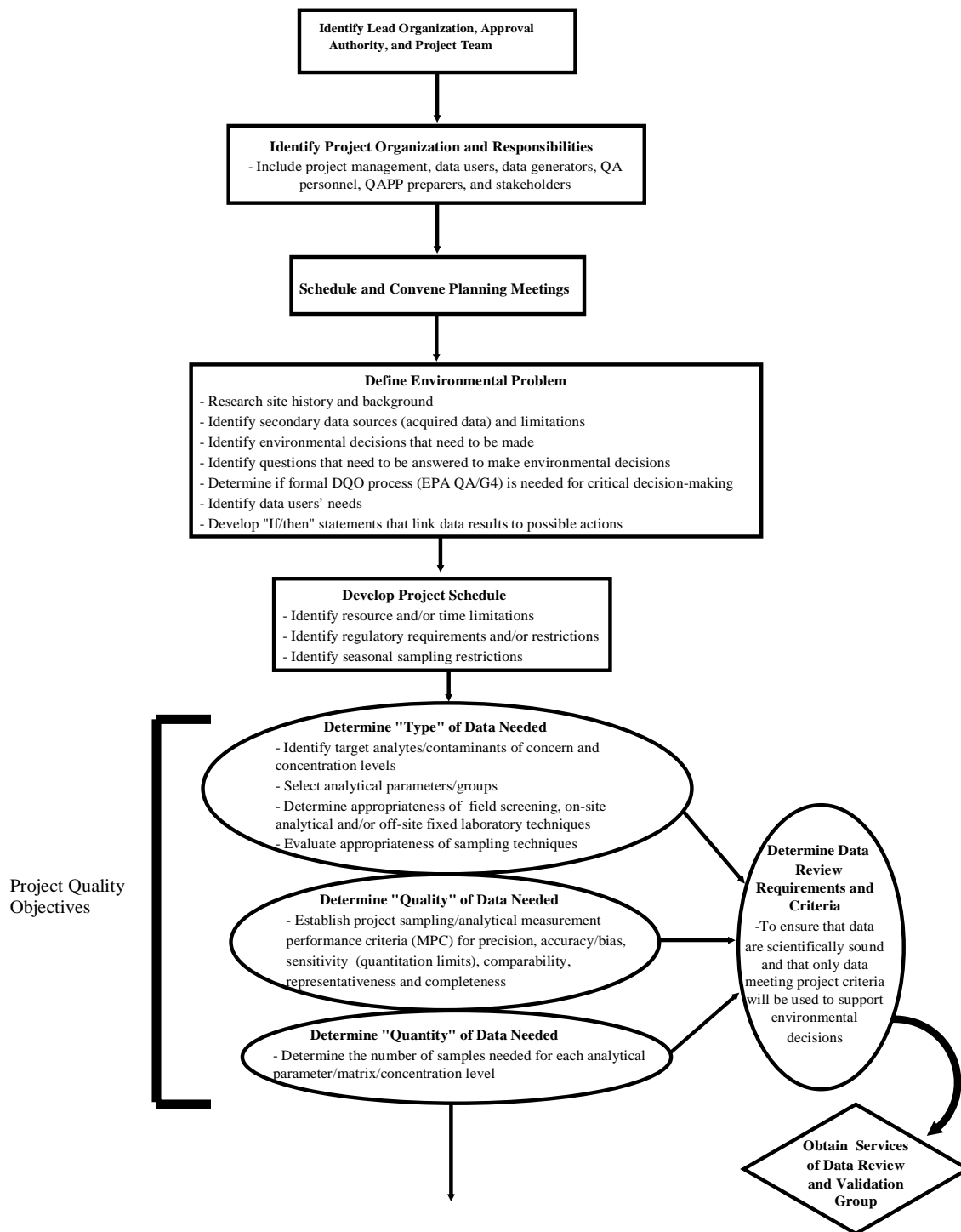
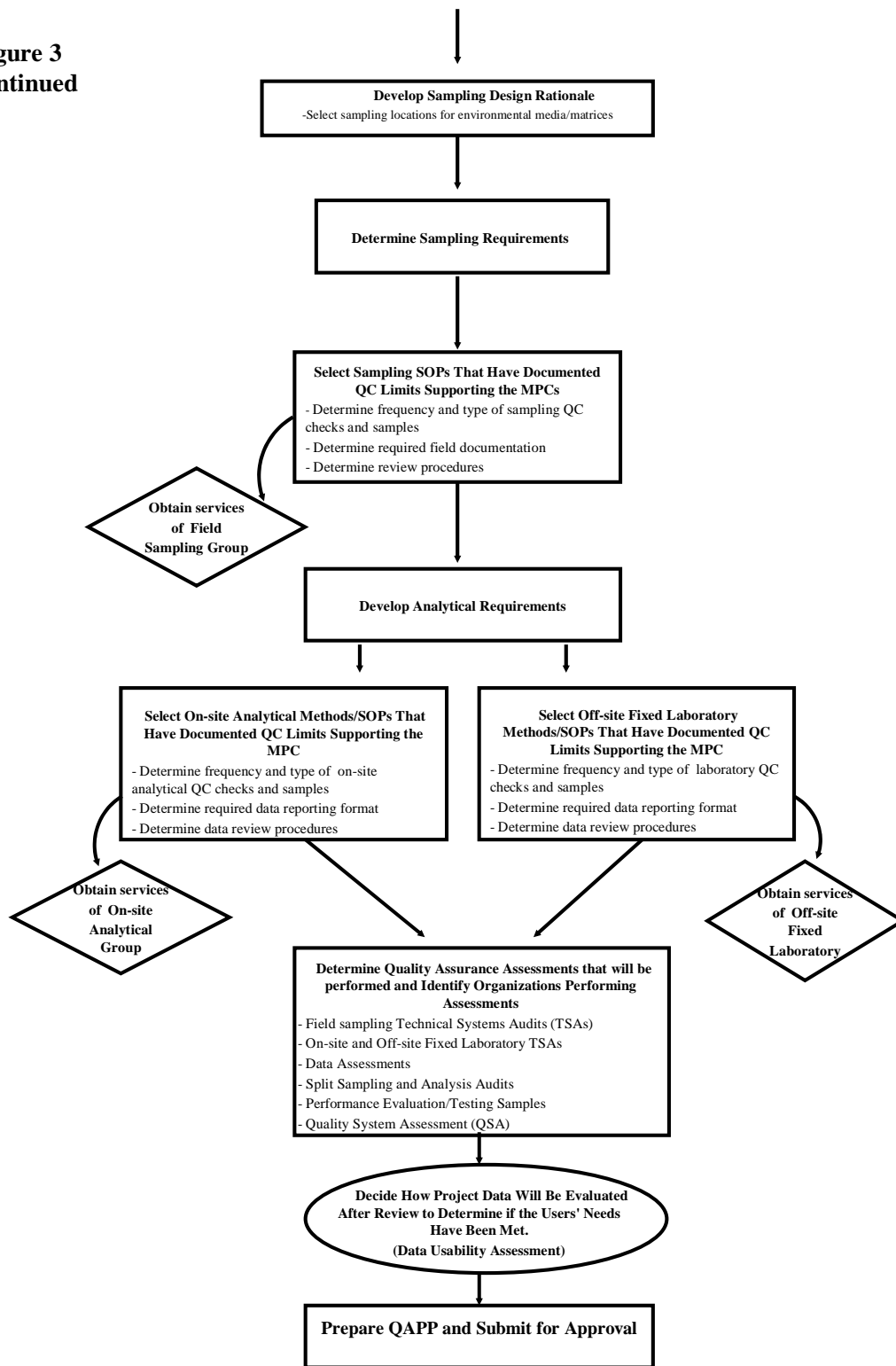


Figure 3
continued



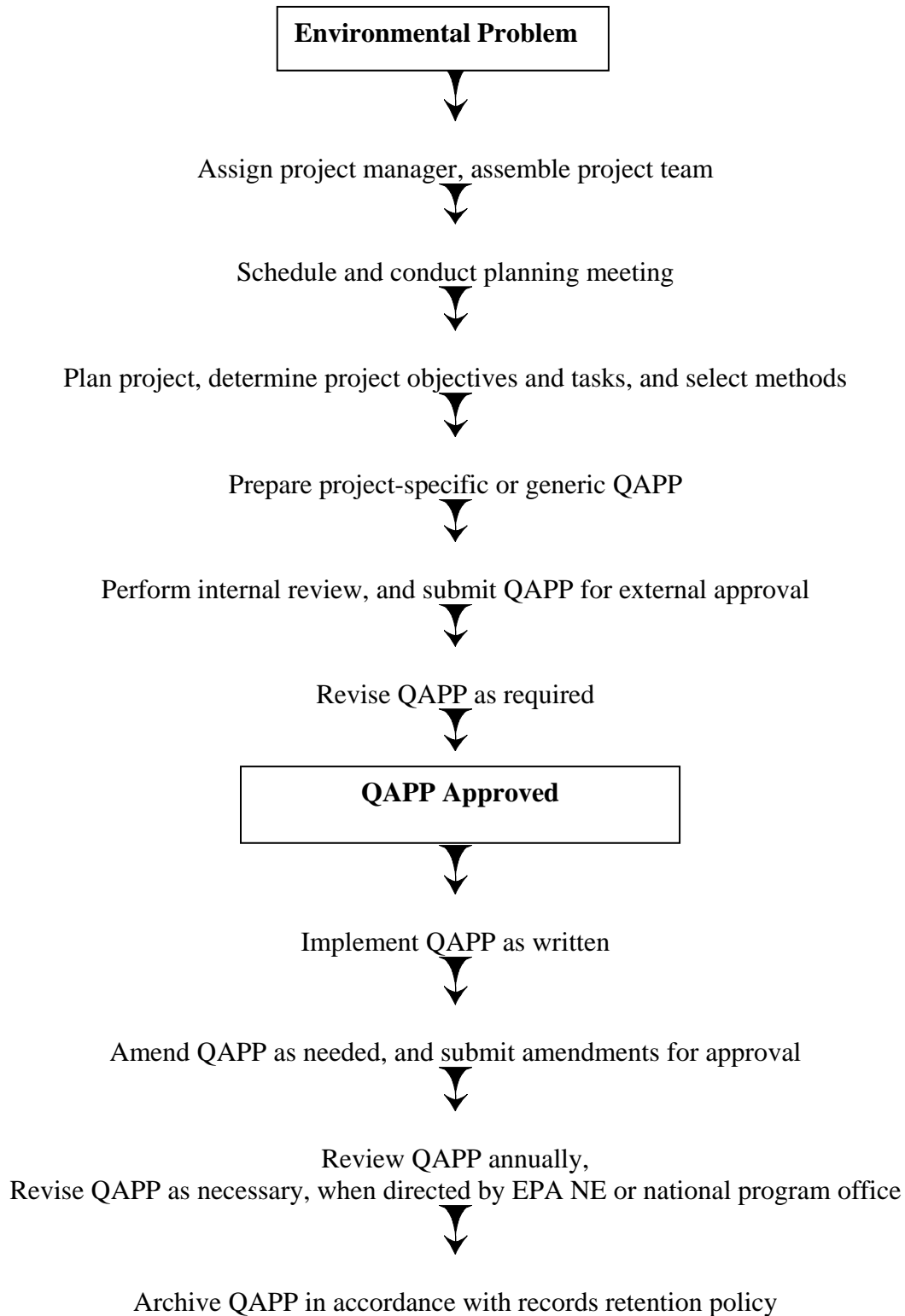


Figure 4. Life Cycle of a QAPP

EPA New England QAPP Program Guidance
Revision 4/05